

## FDA Doesn't Have The Discretion It Thought It Had

*Law360, New York (April 26, 2012, 1:28 PM ET)* -- Of all the areas in which we'd have expected to see the U.S. Food and Drug Administration's (FDA) discretionary wings clipped, drugs used in lethal injection executions didn't come to mind. But we recently read *Beaty v. FDA*, 2012 U.S. Dist. LEXIS 41397 (D.D.C. Mar. 27, 2002), and that's exactly what it involved. It provides an unexpected but indisputably interesting backdrop for the discussion.

In *Beaty*, a group of death row inmates challenged the FDA's decision to allow certain states to use thiopental, an anesthesia drug imported from foreign countries, as part of lethal injection executions — in particular, the plaintiffs' executions. The inmates claimed that imported thiopental was (i) "misbranded" and (ii) its use was "unlawful" because it was not FDA-approved.

Interestingly, both of these points were undisputed. *Id.* at \*9-10. So the *Beaty* decision is focused, instead, on the FDA's use of discretion to nonetheless allow states to use thiopental. There were two particularly interesting aspects to the court's opinion.

First, the court found that U.S. Congress never gave the FDA this discretion. The FDA's powers come from the Federal Food, Drug & Cosmetics Act (FDCA). And the court found that FDCA §381(a) requires the FDA to destroy or allow to be exported any foreign drugs that are misbranded or not approved, under FDCA §355. It doesn't say, "FDA, use your discretion":

"If it appears' the imported product 'is ... misbranded, or in violation of 21 U.S.C. section 355, ... then such article shall be refused admission [into the U.S.].' [I]f an imported article is refused admission, the Secretary of the Treasury 'shall cause the destruction of any such article' unless it 'is exported ... within 90 days.'"

*Id.* at \*5 (quoting FDCA §381(a)).

As most of us know, "shall" generally means "must," not "do what you think is best." That's how the *Beaty* court read it:

"[I]t is clear that in Section 381(a), Congress's intent was for 'shall' to impose a mandatory obligation on defendants to refuse to admit the misbranded and unapproved drug, thiopental, into the United States."

*Id.* at \*24.

The FDA tried to find for itself this discretion by pointing to *Heckler v. Chaney*, 470 U.S. 821, 831-33 (1985). In *Heckler*, the U.S. Supreme Court deferred to the FDA's decision not to bring an enforcement action, holding that the FDA had "prosecutorial discretion," much like a prosecutor, to decide not to bring an enforcement action.

True, but the *Beatty* case was different. It didn't involve discretion to bring an enforcement action. It involved a directive from Congress:

"Unlike in *Heckler*, here, the FDA's decision did not involve a decision whether to initiate enforcement proceedings against a violator of the Act; rather, it involved a decision to ignore an administrative directive. ... [T]he FDA was being called on to follow an administrative procedure established by Congress. ... [T]he FDA was required under the FDCA to reject the shipments in the interest of public safety."

2012 U.S. Dist. LEXIS 41397, at \*26.

"Shall" meant "must," and the court held that the FDA couldn't manufacture discretion from this language.

Second, the court determined that the FDA's decision was arbitrary and capricious because it acted inconsistently with its longstanding practice regarding foreign drugs.

In past practice, the FDA issued multiple letters to states who wanted to allow importation of cheaper foreign drugs, and the FDA took the position that use of such drugs would likely violate the FDCA and would be detained by the customs department.

The FDA in fact responded to California's request to import cheaper drugs with a letter stating that such importation would violate the FDCA in almost every instance. 2012 U.S. Dist. LEXIS 41397, at \*31.

Against this background, the *Beatty* court determined that the FDA had changed its practice when addressing thiopental and that this change made little sense. The court used strong language, complete with exclamation point, to describe what it saw as overreaching:

"This departure from longstanding policy makes little sense in light of the fact that alternative barbiturates for use in lethal injection protocols exist. ... Put simply, this appears to be nothing more than the FDA, once again, stubbornly clinging to every last ounce of its discretionary authority!"

Id. at \*32.

Strong words. The court granted summary judgment and ordered the FDA to no longer permit thiopental into the country and to tell states that its use is prohibited by law. Id. at \*36.

The FDA's discretion — and its authority for it and consistency with it — comes up in our practice often, from rulemaking to enforcement decisions to actions and less formal practices that fall somewhere in between. So it will be interesting to follow whether and, if so how, the *Beatty* case proceeds through the appellate process.

--By John J. Sullivan, Dechert LLP

John Sullivan is a partner in Dechert's Princeton, N.J., office.

The opinions expressed are those of the authors and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

All Content © 2003-2012, Portfolio Media, Inc.